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**Sent:** 4/12/2011 7:17:28 PM  
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**Subject:** NEWS UPDATES: EPA Advances Key Risk Studies, Partially Bypassing Dispute Over Lab's Data (Risk Policy Report)

## EPA Advances Key Risk Studies, Partially Bypassing Dispute Over Lab's Data

**Posted: April 11, 2011**

EPA is seeking to advance the half-dozen risk assessments that it stalled last summer due to concerns about data from a controversial Italian laboratory that the assessments reference, even before federal scientists complete their long-awaited pathology working group (PWG) review of Ramazzini laboratory's data.

The agency last year announced that it was stalling its draft assessments of methanol, the fuel additives methyl tertiary butyl ether (MTBE) and ethyl tert-butyl ether (ETBE), and the plastic ingredient acrylonitrile, pending EPA's further review of Ramazzini Institute studies used in the assessments (*Risk Policy Report*, June 22).

The agency said it was also "reviewing" its finalized assessments of vinyl chloride and 1,1 dichloroethylene -- published on the IRIS website in 2000 and 2002 respectively -- "to determine what action is needed to assure their scientific integrity."

The delays were prompted by an initial review of Ramazzini data, conducted by the National Institute of Environmental Health Sciences (NIEHS), that purportedly showed fewer incidence of cancer in test animals exposed to methanol than the laboratory had initially reported. That assessment reviewed 10 percent of the Ramazzini Institute's tissue slides from its methanol cancer bioassay, according to a Methanol Institute spokesman.

Now EPA is confirming in an April 11 statement that while its long-awaited PWG is underway, it will continue its assessments of three of the chemicals: acrylonitrile, ETBE and MTBE. The announcement indicates that "EPA has determined that reliance on Ramazzini Institute study results is not necessary to continue with assessment development for MTBE, ETBE and acrylonitrile, including an assessment of cancer risks. Therefore, work on the assessments for the three chemicals will continue during the PWG review." And EPA says it will split its methanol assessment in two, and proceed with its analysis of the non-cancer risks of methanol because it did not rely on Ramazzini's data for this part of the assessment. That document "will be released shortly," according to the announcement.

EPA's assessment of methanol's cancer risk, plus its assessments of the two remaining chemicals, vinyl chloride and 1,1-dichloroethylene, await the completion of the PWG that EPA and NIEHS are jointly sponsoring.

"The [PWG] review has begun and will continue over the next several months. The results will be made public and the cancer assessment for methanol will remain on hold until its completion," according to the agency's statement, which adds that EPA will "evaluate the results of the PWG review to inform conclusions about Ramazzini Institute tumor findings for" 1,1-dichloroethylene and vinyl chloride.

The Methanol Institute is already praising the agency's announcement, including the agency's first public pronouncement that it will conduct the PWG. "We are certainly pleased the full PWG is moving forward," a spokesman for the institute says. "We expect the full PWG will likely follow the findings of the preliminary PWG, which found far fewer" incidents of cancer in lab animals than Ramazzini reported.

The institute's spokesman adds that he expects the full PWG will "confirm that the entire colony of rats has widespread respiratory disease and other infections." Industry has long argued that Ramazzini's findings of cancer in its rats exposed to methanol and other chemicals, such as MTBE, are confounded by a respiratory infection in its lab animals.

"We believe the Ramazzini methanol study can't be used," the spokesman says. "By extension, there is really no reason to believe that methanol is a carcinogen." -- *Maria Hegstad*

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